REMARKS

The Office Action dated September 25, 2006, has been reviewed in detail and the application has been amended in the sincere effort to place the same in condition for allowance. Reconsideration of the application and allowance in its amended form are requested based on the following remarks.

Applicants retain the right to pursue broader claims under 35 U.S.C. §120.

Applicants have provided a unique solution with respect to problems regarding DNA EXPRESSION CONSTRUCT FOR THE TREATMENT OF INFECTIONS WITH LEISHMANIASIS. Applicants' solution is now claimed in a manner that satisfies the requirements of 35 U.S.C. §101, §103, and §112.

Rejection of Claims 1-18 Under 35 U.S.C. §103:

Claims 1-18 were rejected under 35 U.S.C. §103, as being unpatentable over Gurunathan et al. in view of Wittig et al. (U.S. Patent 6,451,593). Claims 1-18 have been canceled herein, without prejudice. New Claims 19-23 will be discussed in view of the present rejection.

Gurunathan, as best understood, generally discloses a method

of vaccination against Leishmania infections. Gurunathan teaches the insertion of the Leishmania antigen LACK into a eukaryotic expression vector as part of a vaccine, which was then introduced into mice to test the effectiveness thereof in combating Leishmania infections in the mice.

Wittig, as best understood, generally discloses a DNA expression construct. In use, the DNA expression construct is injected into muscle or skin, which leads to the expression of the antigen(s) encoded in the DNA of the expression construct.

The Examiner stated that "it would have been *prima facie* obvious to the skilled artisan at the time of filing to use a dumbbell DNA construct encoding p36 LACK linked to a peptide according to the teachings of Wittig instead of a plasmid construct in the methods of immunizing against Leishmania taught by Gurunathan et al." The Examiner further stated that "based on the substantial guidance for making dumbbell constructs provided by Wittig et al., the skilled artisan would have had a reasonable expectation of success in making a dumbbell DNA expression construct encoding the p36 LACK antigen covalently linked to a peptide such as the NLS peptide from SV40."

MPEP 2143 sets forth the basic requirements for a *prima facie*

case of obviousness as follows:

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.
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> The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

It is respectfully submitted that the above combination fails to satisfy all of the requirements of MPEP 2143 with respect to the new claims presented herein. The references, either taken singly or in any reasonable combination thereof, do not teach or suggest all of the claim limitations as required. In contrast to the applied references Claim 19 recites a "method of vaccinating a living being against infections by leishmania using a vaccine comprising immunizing polynucleotide sequences; said polynucleotide sequences comprising DNA expression constructs." Claim 19 further recites DNA expression constructs that each comprise single strands "comprising: a terminator sequence, and a coding sequence encoding at least the p36 LACK antigen under control of a promoter sequence operable in the living being that is to be immunized; said DNA expression

construct being covalently linked to at least one oligopeptide to increase transfection efficacy; said at least one oligopeptide comprises 3 to 30 amino acids; at least half of said amino acids of said at least one oligopeptide are members of the group comprising arginine and lysine." Claim 19 also sets forth the steps of "injecting said vaccine comprising said DNA expression constructs into a living being; and eliciting, with said DNA expression constructs of said injected vaccine, an immune response in the living being against infections by leishmania." It is respectfully submitted that Wittig and Gurunathan do not teach or suggest the above limitations.

Also in contrast to Wittig and Gurunathan, Claim 21 recites a "method of making a vaccine for vaccinating a living being against infections by leishmania using a DNA expression construct comprising covalently-closed, linear deoxyribonucleotide molecules." Claim 21 further recites the steps of: "constructing plasmid pMOK p36; covalently attaching an NLS peptide comprising amino acid sequence PKKKRKV (Seq ID 3) to oligonucleotides; and producing, using said plasmid pMOK p36 and NLS-attached oligonucleotides, said DNA expression construct and thus a vaccine for vaccinating a living being against infections by leishmania." It is respectfully submitted that Wittig and Gurunathan do not teach or suggest the above limitations.

Finally in contrast to Wittig and Gurunathan, Claim 22 recites a "vaccine for vaccinating a living being against infections by leishmania." Claim 22 also recites "said double-strand-forming single strands comprising: a terminator sequence, and a coding sequence encoding at least the p36 LACK antigen under control of a promoter sequence operable in the living being that is to be immunized; said DNA expression construct being covalently linked to at least one oligopeptide to increase transfection efficacy; said at least one oligopeptide comprises 3 to 30 amino acids; at least half of said amino acids of said at least one oligopeptide are members of the group comprising of arginine and lysine." It is respectfully submitted that Wittig and Gurunathan do not teach or suggest the above limitations.

The Examiner also stated that there would be a reasonable expectation of success, in view of the teachings of Wittig and Gurunathan, in making a dumbbell DNA expression construct encoding the p36 LACK antigen. It is respectfully submitted that the art of biology and genetics is very unpredictable. It is extremely difficult, if not impossible, to have any reasonable expectation of success when combining teachings. It is respectfully submitted that the combination of p36 LACK antigen and the expression construct of

Wittig would lead to a suitable vaccine or method of vaccination for immunization against Leishmaniasis. There is no reason for a person of ordinary skill in the art to expect that this combination would work as an efficient vaccine for the treatment of such infections. It is respectfully submitted that it is well known in the field of biology and genetics that the mere combination of an expression construct with a coding sequence for an antigen against a particular infection will not provide a reasonable expectation or prediction of success.

In view of the above, it is respectfully submitted that only upon a reading of the present application would one find the motivation or reasonable expectation of success in combining the p36 LACK of Gurunathan with the expression construct of Wittig. Such hindsight analysis is improper according to MPEP 2143, which states that the "teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure" (emphasis added).

It is respectfully submitted that Claims 19, 21, and 22 each distinguish over and are not rendered obvious by Wittig or Gurunathan, either taken individually or in any reasonable combination thereof. Claims 20 and 23 are also believed to distinguish over Wittig and Gurunathan based on their dependence

from Claims 19 and 22, respectively, and for the distinguishing limitations recited therein.

In view of the above, reconsideration and withdrawal of the present rejection is respectfully requested.

Rejection of Claims 6 and 9-13 Under 35 U.S.C. §101 and §112, Second Paragraph:

Claims 6 and 9-13 were rejected under 35 U.S.C. §101 and §112, second paragraph, because the claimed recitation of use resulted in the claims being improper method claims as they did not set forth any method steps. Claims 1-18 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The specific reasons for these rejections are set forth on pages 6-7 of the outstanding Office Action.

Claims 1-18 have been canceled herein, without prejudice, and Claims 19-23 are newly presented herein. It is respectfully submitted that Claims 19-23 have been drafted in a manner believed to conform to the requirements of 35 U.S.C. §101 and §112, second paragraph.

Objections to the Specification:

The Examiner objected to the specification for the reasons set forth on pages 2-3 of the outstanding Office Action. The specification has been amended herein in a manner believed to overcome these objections and comply with the Examiner's requirements.

Double Patenting:

Claims 1-18 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7-11, and 17-20 of copending Application No. 10/816,465. Claims 1-18 have been canceled herein, without prejudice, and new Claims 19-38 have been presented herein. It is respectfully submitted that the amendments to the claims have rendered the present rejection moot as the new claims are patentably distinct from the claims of Application No. 10/816,465.

Priority Documents:

The Examiner noted on page 2 of the outstanding Office Action that certified copies of the foreign priority documents DE 101 48 732.0 and DE 101 56 679.4 have not been filed. The certified

copies of these documents are being filed by mail under separate letter.

Petition for Extension of Time under 37 C.F.R. §1.136(a):

Applicants hereby petition for a one-month extension of time, from December 25, 2006 until January 25, 2007, in which to file the present amendment in the above-cited case. A payment in the amount of $60.00, representing the one-month extension fee for a small entity, is submitted herewith.

Art Made of Record:

The prior art made of record and not applied has been carefully reviewed, and it is submitted that it does not, either taken singly or in any reasonable combination with the other prior art of record, defeat the patentability of the present invention or render the present invention obvious. Further, Applicants are in agreement with the Examiner that the prior art made of record and not applied does not appear to be material to the patentability of the claims currently pending in this application.

In view of the above, it is respectfully submitted that this application is in condition for allowance, and early action towards

that end is respectfully requested.

Leave to Delay Treatment of Formal Objections Until Allowable Subject Matter is Indicated:

In accordance with 37 C.F.R. §1.111, it is hereby respectfully requested that any objections or requirements not fully treated and set forth in the outstanding Office action that relate to form and are not necessary to further consideration of the now pending claims, be held in abeyance until allowable subject matter is indicated.

Summary and Conclusion:

It is submitted that Applicants have provided a new and unique DNA EXPRESSION CONSTRUCT FOR THE TREATMENT OF INFECTIONS WITH LEISHMANIASIS. It is submitted that the claims presented herein are fully distinguishable from the prior art. Therefore, it is requested that a Notice of Allowance be issued at an early date.

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Alexandria, VA 22313-1450, on the date indicated in the certification of mailing on the transmittal letter sent herewith, or if facsimile transmitted, I, the person signing this certification below, hereby certify that this paper is being facsimile transmitted to the United States Patent and Trademark Office on the date indicated in the certification of facsimile transmission on the transmittal letter which is being facsimile transmitted herewith.

Respectfully submitted,

/Nils H. Ljungman/

Nils H. Ljungman, Esq.
Attorney for the Applicant
Reg. No. 25,997
Name of person signing certification
Nils H. Ljungman & Associates
P.O. Box 130
Greensburg, PA 15601-0130
Telephone: (724) 836-2305
Facsimile: (724) 836-2313